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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,723	12/06/2001	Mark G. Allen	BVTP-P04-506	4309

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EXAMINER

WITCZAK, CATHERINE

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/010,723	Applicant(s) ALLEN ET AL.	
	Examiner Catherine N. Witczak	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 49-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 49-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Witczak
3/2/07

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant claims that the substrate and/or the microneedles are formed from flexible material to allow the device to fit the contour of the biological barrier. This recitation is not enabled as the specification provides no details as to what Applicant considers such flexible materials.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 49-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al (US 3,964,482).

Claims 1, 49-61, and 70: Gerstel et al disclose in column 7, lines 52-68 the microneedle having a length between 1um and 1mm and a diameter between 1um and 100um with an annular channel extending from the base to the tip (Figure 1), having either a conical or tapered tip (Figures 1 and 2) and being angled at

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about 90. Gerstel et al further disclose in columns 10-11 the substrate (14) and/or the microneedle being formed from flexible materials.

Claims 62-68: Gerstel et al disclose in column 8, lines 30-60, column 9, lines 29-35 and column 10, lines 55-column 11, lines 63 that the microneedles can be made of a material consisting of a metal, and metal alloy, a biodegradable polymer or a non-biodegradable polymer.

Claim 69: Gerstel et al disclose in column 8, line 60-column 9, line 41 and column 11, lines 20-51 the microneedles can be formed by a micromachining technique selected from lithography, etching, thermal oxidation of silicon, electroplating, electroless plating, diffusion, ion implantation, film deposition, sputtering, chemical vapor deposition, epitaxy, or anodization.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al as modified by Eicher et al (US 6,132,755).

Gerstel et al disclose the claimed invention except a transport control mechanism for generating a voltage field gradient for causing the material to move across a biological barrier. Eicher et al discloses a transport control mechanism for generating a voltage field gradient for causing the material to move

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across a biological barrier in column 5, lines 48 – column 6, line 8. It would have been obvious to one with ordinary skill in the art to modify the system as taught by Gerstel et al with a transport control mechanism for generating a voltage field gradient for causing the material to move across a biological barrier as taught by Eicher et al since such a modification would increase the migration of the drug across the skin barrier and improve absorption.

3. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al as modified by Godshall et al (US 5,879,326).

Gerstel et al disclose the claimed invention except a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier. Godshall et al discloses a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier in column 2, lines 7-16. It would have been obvious to one with ordinary skill in the art to modify the system as taught by Gerstel et al with a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier as taught by Godshall et al since such a modification would increase the migration of the drug across the skin barrier and improve absorption.

Response to Arguments

Applicant's arguments filed 12/28/2007 have been fully considered but they are not persuasive. Gerstel et al disclose in column 10, line 55 – column 11, line 2 the projections being made out of polymers such as polyethylene, PTFE, etc which are well known to be flexible and thus would inherently be capable of allowing the device to fit the contour of a barrier. Applicant has not provided in the claim nor in the specification any degree of flexibility the device must have, nor the extent to which it must fit the contour of the biological barrier.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witzak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Simons

3/3/08